

Manufacturing Consensus

BY DAVID HEALY

Readers opening any issue of any major medical journal are likely to see both glossy drug advertisements and staid reports on clinical trials. There might seem to be an obvious problem here—too many adverts leading physicians astray—with an equally obvious answer—not enough clinical trial reports providing solid evidence. Of course, physicians interviewed at the “educational meetings” held in expensive resorts report that they are impervious to sales tactics; they are driven only by evidence. Unfortunately, the problem, the answer, and physicians’ reliance on evidence are all much more complicated than they at first appear to be.

For some time, a more careful answer has focused on the fact that companies do not publish negative results: they do not report trials which suggest that a drug does not work. This led to calls for a registry of all clinical trials, so that the public can learn about unpublished research.

Recent events, though, have revealed a still deeper problem. A Glaxo SmithKline trial, study 329, which looked at the effects of the antidepressant paroxetine in depressed minors, was a negative trial, but one that was published—sort of: Glaxo SmithKline published selected positive results. The final article stated that paroxetine was safe, well-tolerated, and effective.¹ Almost all other articles describing controlled trials of antidepressants in minors have made identical statements. As a result of regulatory concerns about the hazards of antidepressants, the results from approximately twenty trials of these agents are now in the public domain, giving us the greatest known divide in medicine between what the raw data from a set of trials show and what the academic literature that purportedly discusses the data claims.

This is a crisis for evidence-based medicine. It stems from the fact that marketing departments, accepting that clinicians are primarily influenced by evidence, have over the past twenty years set about providing that evidence in the

best journals and with the best authors. But we now know that the authors may not be the writers: it is coming to light that many articles are ghostwritten.² Thus the problem is not just a matter of accessing unpublished trials; it is that we may not be able to trust the results of any published trials.

When the 1962 amendments to the U.S. Food and Drugs Act were put in place, physicians’ ability to weigh evidence was seen as one check on companies’ promotional excesses. The power of the FDA to regulate advertising claims was another. But companies realized that the FDA cannot regulate what academics say. If after due consideration of the published evidence, individual academics endorse

a product, or consensus panels build that product into guidelines and algorithms that dictate treatment options, which then can be built into advertisements, the FDA will not intervene.

What physicians have failed to see is that marketing departments seek to understand them better

than they understand themselves—playing even on their sense of imperviousness to trinkets and junkets. Rather than selling the product, marketing departments seek to guide the way physicians think.

In the course of the twentieth century, marketing has been incorporated into all areas of our life, even religion. There must, however, be some fundamental opposition between marketing and science; the one operates by building consensus, the other by fracturing it. Against this background, the only way to maintain therapeutics as a science at this point would seem to be through independent access to the raw data of clinical trials. Registering the mere existence of unpublished trials will not suffice.

1. M.D. Keller et al., “Efficacy of Paroxetine in the Treatment of Adolescent Major Depression: A Randomized, Controlled Trial,” *Journal of the American Academy of Child and Adolescent Psychiatry* 40 (2001): 762-72.

2. D. Healy and D. Cattell, “The Interface between Authorship, Industry and Science in the Domain of Therapeutics,” *British Journal of Psychiatry* 182 (2003): 22-27.

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